

REMARKS

Claims 1-4, 12, 13, 24, and 27-30 are pending in the application. Claims 1-5, 12, 13, 24, and 26-30 were under active consideration. By amendment herein, claims 24 and 25 have been canceled, without prejudice or disclaimer. Claim 1 has been amended as shown above to exclude plasmid delivery. Entry of this amendment is respectfully requested.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

Information Disclosure Statement

Applicants mistakenly listed 08/878,373 on the previously submitted IDS and are submitting a revised IDS to correct the inadvertent typographical error. Applicants intended to disclose copending U.S. Application Serial No. 08/838,373 and again also direct the attention of the Examiner to the prosecution history of this application.

Rejection under 35 U.S.C. § 102(a)

Claims 1-5, 24, and 26-30 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by the reference of Fuller et al. (J. Med. Primatol. 25:236-241). In particular, the Office Action alleges that “Fuller et al. teaches a prime boost strategy for immunizing a mammal against HIV comprising the administration of a naked DNA plasmid encoding the gag, pol, and env proteins from HIV, followed by the administration of recombinant HIV gp120 envelope protein” (Office Action, page 4).

For a reference to anticipate claimed subject matter under 35 U.S.C. § 102, “the reference must teach every aspect of the claimed invention either explicitly or implicitly.” M.P.E.P. § 706.02. Applicants respectfully submit that the reference of Fuller et al. does not teach all aspects of the Applicants’ invention, either explicitly or implicitly.

The reference of Fuller et al. discloses induction of HIV- and SIV-specific immune responses by DNA immunization with **plasmid** vectors encoding gp160 and gp120 following boosting with recombinant HIV or SIV antigens. Claim 1, as currently amended, specifically recites vectors which may be used and does not include plasmid vectors. The reference of Fuller

et al. does not disclose induction of an immune response using a retroviral vector, an alphavirus vector, a parvovirus vector or a eukaryotic layered vector initiation system vector. Therefore, the reference of Fuller et al. fails to teach all the limitations of the claims, and withdrawal of the rejection under 35 U.S.C. § 102(a) is respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 1-3, 5, 12, 13, and 27-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the reference of Dubensky et al. WO 95/07994 (1995) in view of the reference of Hu et al. (1991) AIDS Res. Hum. Retrovir. 7:615-620. Applicants respectfully traverse the rejection.

In particular the Office Action alleges:

Dubensky et al. teaches alphavirus vectors and layered eukaryotic vector initiation systems comprising sindbis, retrovirus or adeno-associated virus vectors capable of expressing a heterologous nucleotide sequence (Dubensky et al., pages 8, and 38-40). Dubensky et al. further teaches the administration of alphavirus vector or layered eukaryotic vector initiation systems capable of expressing an antigen to warm-blooded animals in order to generate an antigen-specific immune response (Dubensky et al., pages 33-36, and 40). In particular, Dubensky et al. teaches the generation of immune responses against hepatitis antigens (Dubensky et al., pages 34-35). In addition, Dubensky et al. teaches that immunostimulatory co-factors can be administered with the antigen (Dubensky et al., page 25).

Dubensky et al. differs from the instant invention as claimed by failing to teach a prime-boost strategy of immunization. Hu et al. supplements Dubensky et al. by teaching that antibody responses against viral antigens can be increased by using a prime boost strategy.

To support an obviousness rejection under 35 U.S.C. § 103, “all the claim limitations must be taught or suggested by the prior art.” M.P.E.P. § 2143.03. In addition, “the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant’s disclosure.” M.P.E.P. § 706.02.

Applicants submit that the cited references do not disclose or suggest all the limitations of the present invention. Thus, a *prima facie* case of obviousness has not been presented by the Office, and the cited combination is based on impermissible hindsight reconstruction.

Dubensky et al. does not teach or suggest the prime boost strategy for immunization of the instant invention, as acknowledged by the Examiner. The reference of Dubensky et al. describes alphavirus vectors and eukaryotic layered vectors for use in DNA immunization;

however, fails to describe or suggest the use of protein antigens for boosting an immune response. Further, the reference of Dubensky et al. does not provide any incentive for using protein antigens in combination with DNA immunization.

The secondary reference of Hu et al. does not cure the deficiencies of Dubensky et al. Hu et al. describes administering recombinant vaccinia virus expressing HIV envelope glycoproteins in combination with gp160 protein for immunization against HIV. Hu et al. does not teach or suggest the use of retroviral vectors, alphavirus vectors, parvovirus vectors, or eukaryotic layered vector initiation system vectors for DNA immunization. Nor does Hu et al. teach or suggest the use of antigens from intracellular pathogens such as bacteria, mycobacteria, parasites, hepatitis virus, or feline immunodeficiency virus for immunization against diseases other than HIV.

Thus, the references do not disclose or suggest all the limitations of the present invention, and the Examiner has not met the burden of establishing a *prima facie* case of obviousness. It is axiomatic that statements in the prior art must be considered in the context of the teaching of the entire reference, and that rejection of claims cannot be predicated on mere identification in a reference of individual components of claimed limitations. *In re Kotzab* 217 F.3d 1365, 55 USPQ2d 1313 (CAFC 2000), the Federal Circuit reversed the finding of obviousness. Indeed, the Federal Circuit repeated that particular findings must be presented as to why a skilled artisan, with no knowledge of the claimed invention, would have selected those components for combination in the manner claimed. *Id.* The Federal Circuit also stated that mere identification of prior art statements that, in the abstract, appeared to suggest claimed limitations does not establish a *prima facie* case of obviousness without a finding as to a specific understanding or principle within the knowledge of the skilled artisan that would have motivated one with no knowledge of the invention to make the combination in the manner claimed (*In re Kotzab*, 55 USPQ2d at 1317):

While the test for establishing an implicit teaching, motivation or suggestion is what the combination of these two statements [in the reference] would have suggested to those of ordinary skill in the art, the two statements cannot be viewed in the abstract. Rather, they must be considered in the context of the teaching of the entire reference. Further, a rejection cannot be predicated on the mere identification [in the reference] of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

Thus, in the absence of some teaching or suggestion in Dubensky and Hu concerning the application of the prime-boost method of immunization as described in the present application, the Examiner has presented no more than an improper hindsight reconstruction of the present invention. As stated by the Court of Appeals for the Federal Circuit *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988): “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” Therefore, the Office has not met the requirements for a *prima facie* showing of obviousness under 35 U.S.C. § 103. For at least the above reasons, withdrawal of the rejection under 35 U.S.C. § 103 (a) is respectfully requested.

CONCLUSION

In light of the above remarks, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned.

The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

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